

## REMARKS

### A. GENERALLY

Claims 9-39 are currently pending in the application. Claims 1-8 have been canceled. Claims 9-39 have been added by amendment.

### B. CLAIM REJECTIONS – 35 USC §102

1. Claims 1-8 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,772,585 issued to Lavin et al. (hereinafter, "Lavin").

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (MPEP §2131; 8<sup>th</sup> Ed., Rev. 1; citations omitted.)

Claim 1, as examined, recited the following limitations:

1. A process for generation of physician notes for patient management via a programmable machine, the process comprising:
  - inputting patient health data reflecting a current state of the patient and treatment objectives for the patient via formatted input options;
  - receiving the patient health data in a healthcare system;
  - creating a customized healthcare profile based on the patient health data;
  - making the patient health data available throughout the healthcare system;
  - remotely programming therapeutic monitoring and delivery systems to provide care to the patient.

The examiner found that Lavin taught all of the limitations claim 1. Examined claim 4, which claim recited the limitation, "setting smart alarms automatically in patient monitoring systems based on the time stamped patient health data," was also rejected as being taught by Lavin. In rejecting claim 4, the examiner found that the "smart alarms" feature was met by "entering progress notes including assessment notes listing conclusions based on subjective and objective observation at step 162 (see column 9, lines 29-40.) The Examiner considers the assessment conclusions (diagnosis or smart alarms) to be based on the subjective and objective observation inputted into the computer." (Office Action, Page 4.)

Applicant respectfully submits that the term "smart alarm" recited in claim 4 refers to a feature of an embodiment in the present application that is described in detail in commonly

owned U.S. Patent 6,804,656 entitled "System And Method For Providing Continuous, Expert Network Critical Care Services From A Remote Location(s)" (herein, the "'656 Patent") the disclosure of which has been incorporated by reference into the current application.

Referring to FIG. 19 the smart alarms of the present invention are illustrated. The smart alarm system constantly monitors physiologic data (collected once per minute from the bedside monitors) and all other clinical information stored in the database (labs, medications, etc). The periodicity of the collection of data is stated for illustrative purposes only. It is well within the scope of the present invention to collect physiological data at more frequent time intervals. Thus, monitor 636 provides information in HL7 form to the interface engine 638. The physiological data is then formatted by the interface engine for storage in the database 640 where all patient information is maintained. The rules engine 642 searches for patterns of data indicative of clinical deterioration.

One family of alarms looks for changes in vital signs over time, using pre-configured thresholds. These thresholds are patient-specific and setting/disease-specific. For example, patients with coronary artery disease can develop myocardial ischemia with relatively minor increases in heart rate. Heart rate thresholds for patients with active ischemia (e.g. those with unstable angina in a coronary care unit) are set to detect an absolute heart rate of 75 beats per minute. In contrast, patients with known coronary artery disease in a surgical ICU have alarms set to detect either an absolute heart rate of 95 beats per minute or a 20% increase in heart rate over the baseline. For this alarm, current heart rate, calculated each minute based on the median value over the preceding 5 minutes, is compared each minute to the baseline value (the median value over the preceding 4 hours). Physiologic alarms can be based on multiple variables. For example, one alarm looks for a simultaneous increase in heart rate of 25% and a decrease in blood pressure of 20%, occurring over a time interval of 2 hours. For this alarm, thresholds were initially selected based on the known association between changes in these two variables and adverse clinical events. Actual patient data were then evaluated to determine the magnitude of change in each variable that yielded the best balance between sensitivity and specificity. This process was used to set the final thresholds for the rules engine.

Alarms also track additional clinical data in the patient database. One alarm tracks central venous pressure and urine output, because simultaneous decreases in these two variables can indicate that a patient is developing hypovolemia. Other rules follow laboratory data (e.g. looking for need to exclude active bleeding and possibly to administer blood).

The purpose of the rules engine is to facilitate detection of impending problems and to automate problem detection thereby allowing for intervention before a condition reaches a crisis state. ('656 Patent, Col. 24, line 43 through Col. 25, line 25.)

As the quoted text makes clear, a "smart alarm" is more than an assessment conclusion made by a computer. In a Notice of Allowability directed to the '656 patent, the examiner cited the following reasons for allowance of claims 30-55 (renumbered in the '656 Patent as claims 1-26):

The present invention comprises independent claims 30 and 46. These claims include the following features that distinguish Applicants' invention over the prior art: utilizing a remote command center in conjunction with a workstation, to monitor and if necessary intervene in the expert critical care of critically ill patients in a plurality of geographically dispersed intensive care units twenty-four hours a day seven days a week by multiple parameters in monitoring and intervention, i.e., [through] a rules engine that use[s] more than one piece of data important to patient care stored in a database. The structure pertaining to the rules engine is set forth for example in Fig. 19 and the Specification where the rules engine (642) searches for patterns [of] data indicative of clinical deterioration on page 39-40. The examiner notes for the record that it has been argued that an intensive care unit can comprise one room on a floor. (Notice of Allowability, page 2.)

Applicant has canceled claim 1 of the application and added new independent claims 9 and 25. New claim 9 recites the following limitations:

A method for utilizing physician notes in a healthcare system comprising:

inputting patient health data reflecting a current state of a patient and treatment objectives for the patient to an input device, wherein the patient health data is inputted via formatted input options presented by the input device and wherein the input device is connected to a network;

receiving the patient health data in the healthcare system via the network;

accessing the patient health care data from a remote command center associated with the healthcare system via the network;

accessing patient data elements of the patient stored in a database from the remote command center via the network;

creating a rule for the patient using the patient health data and the patient data elements;

applying a rules engine to selected patient data elements stored in the database to

search for patterns of data and to produce an output indicative of a change in the medical condition of the patient; and  
utilizing the output from the rules engine to determine if intervention is warranted,  
wherein the monitoring and determining if intervention is warranted for the patient is directed from the remote command center.

Independent claim 25 recites similar limitations.

Applicant respectfully submits that Lavin does not teach or reasonably suggest creating a rule from the patient health data collected from the physician notes and applying that rule against patient data elements using a rules engine.

Based on the foregoing, Applicant submits that claims 9-39 are not anticipated by Lavin and are therefore allowable over the cited prior art.

#### C. CONCLUSION

Applicant respectfully requests reconsideration of the current rejection of the claims now pending in this application in view of the above amendments, remarks and arguments. Should any further questions arise concerning this application or in the event the above amendments do not place the application in condition for allowance, applicant respectfully requests a telephone interview. Attorney for the applicant may be reached at the number listed below.

Respectfully Submitted,

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